Plugs for Drugs

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UNLESS YOU ARE A health professional, chances are you have not encountered an advertisement for prescription drugs. This is by design. The Food and Drug Administration (FDA) has long discouraged direct advertising of prescription drugs to consumers. From 1983 until September 1985, there was actually a moratorium on all advertising of specific prescription drugs other than simple price advertising. Concerned about a possible surge in pharmaceutical advertising, the FDA set the moratorium as a time for discussion and research.

While the moratorium has now been lifted, advertising to consumers is still discouraged by the extensive disclosure requirements that have existed for 20 years. Under the requirements, an advertisement that promotes a drug for a particular use is prohibited unless it contains a "brief summary" of "all necessary information" on side effects and contraindications. These summaries are anything but brief when compared with typical consumer-directed advertisements; they often occupy a full page of tiny print. Any possible enthusiasm for advertising to consumers must surely collapse under the weight of the disclosure requirements.

It is commonly believed that discouraging direct advertising makes sense. The reasons given are that advertisements, if not carefully regulated, would encourage unnecessary or unwise prescriptions to be written and that the cost of advertising would be passed along to patients in the form of higher prices. In our opinion the opposite is true: prescription drug advertising is likely to make consumers healthier and save them money at the same time.

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What is Regulated and What is Not

Prescription drug advertising to consumers is regulated by the FDA under the authority of the Drug Amendments of 1962. As recently restated in the *Federal Register*, "law and regulations governing prescription drug advertising require, with certain exceptions, a brief summary of all necessary information related to side effects and contraindications in any advertisement that promotes a drug for a particular use." Without the brief summary, no mention may be made of the physical condition for which a drug is used. In practice, any advertisement which does more than name a drug—or point to it—and list its price must be coupled with a statement of side effects and contraindications. An advertisement which would escape the disclosure requirements would be one, for example, which discussed the symptoms of a disease and urged individuals to seek medical attention without naming or suggesting a particular product. The disclosure requirements apply to all prescription drug advertising, whether aimed at consumers or physicians.

These regulations stand in stark contrast to those governing over-the-counter drug advertis-

ing. As any television viewer knows from, say, an Excedrin advertisement, drug makers can advertise over-the-counter drugs by name and make health claims without mentioning side effects or contraindications. Over-the-counter drug advertising is regulated by the Federal Trade Commission only for deception; in general, there are no positive disclosure requirements. The more lenient treatment of over-the-counter drug advertisements is somewhat paradoxical given that these drugs may be purchased in unlimited quantities and without physician involvement. In the case of prescription drugs, a physician can not, by law, be omitted from the prescription process.

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The Deterrent to Advertising

The FDA regulations discourage direct advertising to consumers. Advertisements that must carry a "brief summary" are not only more costly to produce and run, but also are more likely to be of limited value to consumers. Information overload may keep consumers from absorbing some valuable information that could be grasped easily if presented simply.

Prescription drug advertisements that escape the disclosure requirements, like those advertisements that were allowable under the moratorium, are generally deterred for another reason—the free-rider problem. An advertisement which urges that medical attention be sought for a certain condition without promoting a particular drug may well increase demand for a class of drugs, but the benefits would be shared by the makers of all similar drugs whether or not they contributed to the cost of the advertisement. Unable to fully capture the gains of such an advertisement, some firms—particularly smaller ones—will find it profitable to allocate expenditures to other marketing strategies. Firms with a large share of the market, due perhaps to manufacturing a drug that has few or no competitors, are more likely to find advertising of unnamed products profitable.

The effect of FDA regulations on the volume and mix of drug advertising activities has been pronounced. While there is relatively extensive advertising of prescription drugs to physicians, carried in medical journals, for example, there is virtually no such advertising to consumers. (Physicians can presumably benefit from information on side effects and contraindications in a way that no particular patient can and are less likely to suffer from information overload.) Advertising of over-the-counter drugs, by contrast, is big business, with hundreds of millions of dollars being spent on it annually.

In the remainder of this paper, we take a look at the "side effects" of regulation—those secondary effects on health and drug prices that have been largely ignored in the debate over prescription drug regulation. Our purpose is not to specify ideal regulations for direct prescription drug advertising. It is simply to point out instances where the cost of the regulatory requirements may impede the spread of useful information and where the information that is required, should direct advertising be undertaken, may be of little use.

The Health Effects of Advertising

Proponents of regulation argue that restricting prescription drug advertising protects people's health. The idea is that advertisements can lead consumers to persuade their physicians to prescribe either too many drugs or the wrong drugs. We agree, but only up to a point. If this were advertising's only effect, the result would certainly be harmful. But there is more to the story. Advertising can improve the match between patients and drugs, and possibly between patients and physicians.

Improving the Patient-Drug Match. The quality of the prescribing process depends on the physician's knowledge of various drugs, the patient's condition, and the interactions between them. Patients themselves can be a source of valuable information if prompted to pass it along. Doctors' questions, of course, can elicit some information, but for each doctor to ask every patient all relevant questions is time-consuming and costly, often much more costly than ad-

vertising that is targeted on those people most likely to be affected. Advertising can be a cost-effective way of prompting the patient to volunteer information about symptoms, treatment experiences, and preferences.

If advertising can improve the match between patients and drugs, it holds the potential for generating substantial health benefits. Some patients would suffer fewer and less unpleasant side effects. Some patients, finding their prescriptions more agreeable, would comply better with their physicians' instructions. (Non-compliance is recognized as a serious problem, with perhaps 30 percent to 50 percent of all patients failing to take medications as prescribed or otherwise ignoring their physician's advice.) Some patients would be induced to move into treatment who otherwise would have foregone it. And, if advertisements lead consumers to lower-priced drugs, as we argue below, fewer prescriptions would be left unfilled and fewer sick people would stay as sick.

Since prescription drugs generally have not been advertised to consumers, we cannot point to direct evidence showing that advertising leads to better matches between patients and drugs. Experience in the over-the-counter drug market offers a close parallel, however. Aspirin and acetaminophen, for example, both widely used over-the-counter pain medications, differ from one another in that aspirin has an anti-inflammatory effect that acetaminophen does not have, but some people experience gastric distress with aspirin and a few are allergic to it. Advertising campaigns for acetaminophen brands have stressed the drug's superiority in terms of being easier on the stomach. That acetaminophen now commands a substantial share of the pain-reliever market demonstrates that some consumers—but not all—prefer the benefit of avoiding stomach distress to the benefit of reducing inflammation. This sorting of customers between products is unlikely to have been accomplished as effectively in the absence of direct-to-consumer advertising.

It could be argued that by requiring drug makers to list all side effects, information is provided which prevents consumers from making fruitless trips to physicians in search of drugs that are poorly suited to them or their conditions. This is not a compelling argument, however. A lengthy and detailed list of all side effects may or may not influence a consumer's decision to request a prescription and, in any event, the first doctor visited could provide all the information necessary or appropriate for the particular consumer. Additional search would not be necessary and thus would not be prevented by the inclusion of brief summaries in advertisements. For those consumers who intend to get a drug one way or another and will shop among physicians until they do, the additional information

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contained in the summaries is of no value. Of course, the information can be of use to no one if, because of the disclosure requirements, manufacturers find it unprofitable to advertise in the first place, which is basically the case today.

By similar reasoning, requiring the brief summaries to include a list of all contraindications (patient conditions that make use of the drug inadvisable) is also of questionable value. Often the conditions included in these lists are what bring patients into treatment to begin with, which means that questions about a drug can be posed during regularly scheduled doctors' appointments. At such times, consumers can obtain all the information, or at least all the pertinent information, that would have been contained in a brief summary. Other contraindications are for conditions about which an ordinary person knows nothing, so the warnings can pass unnoticed. For either of these reasons, disclosure of contraindications or side effects may not play a useful role but rather, by discouraging advertising, serve only to deter the broadcast of useful, health-improving information.

The overall usefulness of the disclosure requirements depends on the relative number of people who are helped and harmed under this regime as compared to a regime in which advertising is regulated only for, say, deception. Suppose that the total number of people who could profit from learning about a drug's availability is large; the drug is inappropriate for only a small proportion of the people attracted by the advertisement; and most of these people cannot identify their own ineligibility for the drug from the advertisement alone and can learn this only

in discussion with a doctor. Advertising, by inducing some individuals to visit physicians to get a prescription for the advertised drug, will thus harm a certain number of people. The number harmed, however, is larger when disclosure is required than when it is not. The reason is that fewer people would get the useful drug since there would be fewer advertisements from which to learn. In addition, people "protected" by the requirement—those who are spared from making an unnecessary trip to the doctor—would, in this example, be relatively few in number.

Certainly there will be cases in which the disclosure of some contraindications in some advertisements might be useful, but the fact remains: requiring all disclosures in all advertisements is certain to discourage the provision of some useful information. Since by law the physician cannot be omitted from the prescribing process, it does not make sense to require that all advertisements give consumers all the information physicians must have.

Expanding Health-Related Information. There are four types of health-related information that advertising can usefully relay. An advertisement can inform the consumer about symptoms which signal a specific disease, drug treatments that are available for a recognized ailment, and side effects—whether feared or experienced—that are more likely with one product than with another. In addition, an advertisement can inform consumers about drugs which carry a relatively high risk, allowing consumers to make their own risk-benefit tradeoffs. Actual advertisements fit these categories well.

Existence of a Disease. Some people who are not well fail to recognize their symptoms as being those of a disease with a possible cure. Either they underrate the significance of their bodies' messages or believe there is nothing that can be done. The sleep disturbances associated with depression and the thirst that comes with diabetes are two such examples. The problem of undertreatment of many diseases, including these, is well-known.

Advertisements can help consumers tie symptoms to specific diseases. This was the aim of the public service advertisements on the "Seven Warning Signs of Cancer"and of a series of advertisements run by Pfizer, a major pharmaceutical firm, about diabetes, hypertension and heart disease. Pfizer's advertisements mention symptoms and urge people to seek diagnosis. Pfizer presumably finds these advertisements for unnamed products worthwhile despite the free-rider problem (it sells the most frequently prescribed oral anti-diabetic drug).

The cost of discouraging this type of advertising by overloading it with informational requirements may be large. To the consumer, the discovery of a possible match between a set of symptoms and a treatable disease is valuable. Because people who do not recognize their symptoms as treatable will not consult a physician about them, physicians are not good substitutes for direct advertising as a means of delivering these messages. At the same time, the process of diagnosis provides a propitious opportunity for doctor and patient to discuss and compare different drugs.

Availability of Treatment. Some people are aware of having a particular disease but do not know that a treatment exists. Advertising can tell them. Smokers, for example, may know that they use a product that is dangerous to their health and yet not know that there is a drug available to assist quitting. During the advertising moratorium, a new smoking-deterrent product, Merrell Dow's Nicorette-brand chewing gum—which, unlike the health hazard it is designed to combat, requires a physician's prescription—could not be advertised by name. Merrell Dow's consumer education campaign did not even state that a new drug product was available, much less that it was a chewing gum. Its advertising copy was vague and at the same time overly comprehensive, saying, among other things, that a physician can help by prescribing "medication to overcome nicotine withdrawal," and providing "materials that address the social and psychological aspects of smoking, and valuable counseling and follow-up." Merrell can now undertake a product-specific advertising campaign but the advertisements would have to include the full panoply of warnings, contraindications and side effects—unlike the very brief rotational warnings in cigarette advertisements. To date Merrell Dow has not found such a campaign worthwhile. Imagine how a crisp advertisement featuring the name "Nicorette" and the fact that Nicorette is a chewing gum might provoke more would-be-nonsmokers to take action.

There are also people who know they are susceptible to particular diseases and would welcome information about the development of drugs to prevent them. Merck Sharp and Dohme recognized this demand for information when

they advertised to carefully targeted audiences the existence of two vaccines. One was a vaccine for hepatitis B, advertised in periodicals whose readership included many homosexuals, a group at special risk. The other was a vaccine against bacterial pneumonia, a problem for older patients; these advertisements appeared in *Modern Maturity* and similar periodicals. Such advertising can have the added effect of inducing individuals to reveal to their physicians important information, such as aspects of their personal lives, that otherwise would be kept private.

While it is possible that useful information on preventatives is exchanged during the course of treatment for other problems or during routine medical examinations, healthy people do not tend to seek doctors' services. It seems wise to augment happenstance with conscious targeting. Advertising can play this useful role.

Side Effects. For most conditions the physician chooses between several drugs, some of which have less frequent or less unpleasant side effects than others. Patients, who are the most familiar with and care most about unpleasant side effects, would benefit from information on how to avoid side effects and would pay attention to advertisements proposing superior therapies. Anyone would be better off if able to switch to an equally effective drug less likely to create discomfort or other objectionable side effects.

Even when all appropriate medications have unpleasant side effects, a patient may prefer one type of discomfort to another. For example, there are some relatively expensive antibiotics that are less likely to cause nausea than other lower-priced products. One patient may prefer the lower-cost version with greater risk of discomfort while another may prefer to pay more in order to have a steady stomach. If the physician does not think to ask the patient's preferences, or does not take the time to do so, the prescription may or may not accord with the patient's preferences. Advertising can inform consumers about the available choices.

Advertising can also help counter a source of non-compliance with prescriptions. Patients who have discontinued a medication because of undesired side effects (perhaps without informing their doctors) might be willing to resume therapy with a more tolerable drug. For example, sexual dysfunction is not an unusual side effect of drugs. Patients may not attribute the problem to their medication and therefore may fail to mention it to their physician. An advertisement indicating a possible cause of the dysfunction would be likely to catch the attention of these patients and lead them, appropriately, to inquire about alternative drugs. Notwithstanding these arguments, the FDA recently denied Ciba-Geigy's request for approval of an advertisement with the message that its anti-hypertensive drug was less likely than some others to cause impotence.

In many cases competition would be sufficient, in the absence of FDA regulation, to get information on side effects to the public. A drug that has fewer or different side effects that can be monitored by patients is likely to be advertised. The advertising of "fewer side effects," in turn, clearly announces that there are side effects in other products. A good example is Merrell's new allergy drug, Seldane, which does not have the common side effect of causing fatigue. Advertising for Seldane (though the drug is not named) emphasizes that it differs from other allergy drugs by not causing this side effect. Research by FTC economist John Calfee on cigarette advertising supports the view that advertisers will refer to negative product characteristics even if that amounts to telling consumers why not to buy the product. Before the FTC banned health claims about cigarettes, rivalrous claims about "mine is less unhealthy" were abundant.

It can be counterproductive, though, to require the listing of side effects. To illustrate, suppose there are only two products that are appropriate for a patient's condition, both of which occasionally cause the same four side effects, but the first product sometimes produces a fifth side effect. The makers of the second product would like to advertise that it is free from that (fifth) side effect, and individuals who experience it with the first product would find the advertising useful. (The first product has no incentive to advertise about side effects.) If the second product must list the other four side effects in order to advertise that it is free of the fifth, the advertising could easily lead consumers to the erroneous conclusion that there is a trade-off between the fifth side effect and the first four (or that the second product has more side effects than the first). In such cases the required disclosures would cause some consumers to avoid the product less prone to side effects. Knowing this, advertisers whose products are superior in terms of side effects will have no incentive to advertise about side effects if full disclosure is required.

Risky Drugs. A similar argument applies to the risk of side effects that are not just unpleas-

ant but that are downright serious. Taking drugs is risky, and someone, either the patient or the doctor, must decide how much risk is worthwhile. When doctors control the information and have the authority to prescribe, the risk level chosen may not match the patient's preferences. Unless patients know something about the risk involved—and doctors may be reluctant to mention it—they cannot make informed choices as to whether to buy a drug if it matches their personal willingness to accept risk or reject it if they are eager to avoid risk. Information conveyed through advertising can stretch the set of options under active consideration; the legal institution of the prescription stands guard against too much foolhardiness on the part of patients.

Improving the Doctor-Patient Relationship

A common concern expressed about advertising is that it could subvert the doctor-patient relationship. We do not think this is likely. To the contrary, advertising can improve two-way communication and strengthen the relationship between the patient and the physician. The improvements in therapy that we posit are likely to make the patient more satisfied with the drugs being taken and with the physician prescribing them. Discussions about drugs could reinforce the personal tie.

It is possible, of course, that advertising will induce some patients to switch doctors, but even this change may be appropriate. A patient should switch to another physician if the wrong medicine is being prescribed, perhaps because the physician's knowledge of medicine is not current, or if the physician cannot explain a prescribing decision satisfactorily. Also if the patient wants a drug that the physician thinks is too risky, this patient and this physician may not be well suited to each other, and again a switch may be beneficial. The prospect of patients switching physicians would have a beneficial side effect—it would enhance incentives for physicians to remain well-informed about drugs.

The Price Effects of Advertising

The second major line of argument used by critics of direct-to-consumer prescription drug advertising is that prices of prescription drugs will have to rise to cover the cost of advertising. This misses a critical point, though: prescription drug advertising can provide useful information. Even if prices rise, consumers may be better off with advertising than without it. Any improvement in the match between drugs and patients will increase the value of drugs to consumers and hence increase the price consumers are willing to pay.

But there is no reason to assume that prices will rise. Economic theory alone does not provide a sure prediction. On the one hand, the increase in costs due to advertising may lead to an increase in price, especially if firms lack price-setting discretion. If advertising serves to make a product more differentiated from its neighbors so that its buyers are more loyal and less sensitive to price, again advertising may lead to a price increase. On the other hand, advertising may reveal the substitutability of products previously thought to be totally different. The increased competition induced by advertising may then lead to price reductions.

Whether advertising raises or lowers prices is an issue that is best resolved empirically. Lee Benham's pioneer study on eyeglasses, published in the *Journal of Law and Economics,* was the first to provide careful evidence showing that the introduction of advertising can lead to lower prices. Subsequent studies have shown similar results for disparate products and markets.

Our examination of the prescription drug market and other indirect evidence suggests that expanded advertising would reduce drug prices by prodding competition.

Shift to Lower-priced Generic Equivalents. Any redirection of prescribing or dispensing behavior from one brand of a drug to a less expensive brand of the same drug lowers the price paid by consumers. And there is ample opportunity for such savings in the prescription drug market. Approximately two-thirds of all prescriptions are for drugs with more than one brand and prices of generic substitutes are often well below those of leading brands. If told about the availability of lower-priced but generally equivalent products, patients would urge their physicians to prescribe the cheaper products or to prescribe generics. An advertising campaign for Rufen, for example, which is Boots' prescription version of ibuprofen, had exactly this purpose: consumers were urged to ask their doctors to prescribe Rufen rather than Motrin, the higher-priced brand first on the market.

Even if physicians do not change the way

they write prescriptions, advertising may lead the consumer to ask the pharmacist to dispense one brand rather than another. About a fifth of prescriptions for multi-source drugs are written generically; for these prescriptions, the drug product to be dispensed must be chosen at the pharmacy. Even when the physician names a brand, substitution between generic equivalents is now legal in all states (within certain limits). While the rate of substitution is still low, it has been increasing rapidly, doubling between 1980 and 1984.

The role of generics is expected to grow as a result of the Drug Price Competition and Patent Restoration Act of 1984, which lowers the cost of entry for generic versions of drugs first marketed since 1962. There has already been a surge of entrants and would-be entrants eager to compete with pioneer products coming off patent.

Generics are now featured in what little advertising there is aimed at consumers. An example is a full page advertisement run by Giant Foods in the *Washington Post* which listed prices for the leading brand and the generics for about 70 different drugs. The problem with advertisements like this one, however, is that by not specifying what the drugs are used for, the audience is restricted to people who recognize drug names. Inclusion of information on conditions treated would expand the audience of these advertisements and encourage price competition among manufacturers.

Shift Among Chemical Compounds. Among several drugs appropriate for a condition, differences in efficacy may be small while differences in prices are large. These relative price differences, if known to consumers, could be an important factor in choice of brands—more important for consumers than for doctors. Consumer-directed advertising that emphasizes price or leads a patient to ask about a drug or its cost should promote price competition.

Competition Among Retailers. Advertising can add vigor to competition among retailers by facilitating consumers' comparisons of the offerings of different stores. Retail price advertising does this directly; national non-price brand advertising does it indirectly, since an assurance that the product is exactly the same wherever purchased enables a shopper to focus on a comparison of price alone. A recent FTC study by Masson and Steiner indicates that retail gross margins are lower for leading brands of prescription drugs than for generics. (Studies of other consumer products have shown the same pattern.) This may be because consumers have more information about leading brands and find it easier to compare prices between stores. Direct advertising would put even greater competitive pressure on retail margins and retail prices.

Reduction in Manufacturers' Prices. By facilitating consumers' comparisons of drugs, advertising can also add vigor to competition between manufacturers—larger and smaller manufacturers of the same or similar drugs, manufacturers of name brands and generics, and manufacturers of existing and new drugs. (As discussed earlier, under the present regulatory regime, manufacturers most likely to advertise despite the free-rider problem are those that already have a substantial share of the market in a particular therapeutic category.) Since buyers are more likely to switch to a product seen as a new therapeutic alternative, and advertising illuminates the alternatives, it can thus make individual drug prices more vulnerable to competitive pressures.

Advertising can add vigor to competition among retailers by facilitating consumers' comparisons of the offerings of different stores.

Other forms of competition in prescription drug markets have led to lower prices. Early antibiotics, for example, showed rapid price declines after a new antibiotic entered the market. The greater the therapeutic advantage of the newly introduced drug, the greater its relative price advantage.

Substitution of Lower-Cost Marketing Techniques. In devising the most efficient mix of marketing activities, pharmaceutical firms have effectively been forbidden one tool, consumer advertising. Marketing activities have therefore been biased toward advertising to physicians, where the marginal effect may be lower than if the same expenditures had been made on advertising to consumers. Allowing pharmaceutical firms to reallocate their marketing resources—without the constraints posed by FDA disclosure requirements—could lead to lower and more effective marketing expenditures. An example of how a pharmaceutical firm might

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Although suggestive, these statistics are not sufficient to conclude that safety caps were completely ineffective on balance. To investigate this hypothesis, trends in the overall aspirin poisoning rate and in the aspirin poisoning death rate are analyzed. In each case, no significant shift in the poisoning rate trend is found to occur with the advent of safety caps in 1972. Although safety caps were first introduced for aspirin, a variety of other product groups such as internal antibiotics and turpentine are also now protected by safety cap requirements. In an analysis of poisoning rate trends for 19 product groups of this type, no significant beneficial effects of safety caps are found.

To investigate the possibility of a spillover effect of safety cap requirements on unprotected products, the poisoning rate trends are analyzed for analgesics that were not covered by safety cap requirements. For these products, the poisoning rate was found to exhibit a significant upward jump beginning with the introduction of safety caps on aspirin. After netting out other factors affecting the poisoning rate trend, the spillover effect is estimated to lead to an increase in the poisoning rate by almost one-fifth. Viewed somewhat differently, 47 percent of the increase in the analgesic poisoning rate between 1971 and 1980 was due to the adverse effect of safety caps on consumer precautions for other products. Overall, there were 3,500 additional analgesic poisonings of children under five each year because of the diminished consumer care that resulted from the introduction of safety caps. In conjunction with the absence of a significant beneficial effect on protected products, these results imply that the net effect of the CPSC requirements was adverse.

The overall verdict is that the regulations issued by the CPSC have failed to produce a demonstrable improvement in safety. The lesson to learn is that the safety of product use is determined both by the characteristics of the product and the actions of consumers. Government regulations influence each of these components of the safety-generating process and may have unintended effects to the extent they lull consumers into a false sense of security and thus lead them to reduce their own precautions. This lulling effect may diminish or offset any beneficial effects of the regulation and ultimately may lead to net adverse consequences for consumer health and safety.

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deal directly with consumers is the way Boots introduced the Rufen brand of ibuprofen. Boots chose not to develop a detailing force but instead offered Rufen in bottles prepackaged for final sale with a consumer rebate coupon fastened around the neck of the bottle.

Conclusions

Under the current regulatory regime, where there is almost no direct-to-consumer prescription drug advertising, consumers forego valuable information on drugs and drug prices, and on disease symptoms, treatments and preventatives. The prescription drug market, in turn, is spared the competitive pressures that would result were consumers better informed. And drug manufacturers and retailers, deprived of an important medium of communication, are restricted to other, possibly more costly marketing strategies. By eliminating excessive disclosure requirements, the advertising of prescription drugs would be encouraged. This would increase the amount of information made available to consumers, improve the match between patients and drugs, and lower drug prices. The gains to consumers—both financially and in terms of their health—could be substantial. ■

Selected Readings

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